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(54) Skin biopsy device and method.

(57) A device and method for performing a skin biopsy procedure, said device comprising a syringe 21 having a detachable needle 25 and a thin sharp cylindrical punch 22 mounted on the same end of the syringe 21 as the needle 25, the punch being only available for excising a specimen for analysis from a patient when said needle is removed from the end of the syringe. The syringe is used to inject a local anaesthetic whereafter the needle is removed to expose the biopsy punch.

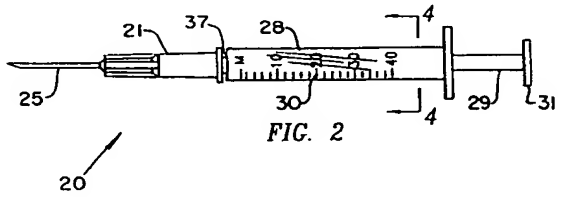

FIG. 2

EP 0 632 996 A1

This invention relates to surgical devices and more particularly to a disposable device for performing skin biopsies.

A skin biopsy is used for diagnosing a skin disorder. The current method for performing a skin biopsy is to anesthetize a biopsy site with a syringe, excise a small cylindrical specimen with a small circular punch for analysis at a pathology laboratory and repair the biopsy site with sutures or butterfly bandages.

The disadvantages with the current method is that it requires several devices, hemostasis and repair of the biopsy site. Moreover, it is time consuming, exposes medical personnel to infection, and because of excessive handling, sometimes damages the excised specimen. Another disadvantage is that there is a likelihood of inducing excessive scar tissue at the biopsy site from sutures or butterfly bandages. Another disadvantage is anxiety occurs in some patients during suturing of wounds.

The present invention is characterized in that a small circular punch is attached to a needle end of a syringe and is exposed only when the needle is detached from the syringe. After a biopsy specimen has been excised with the punch, a circular absorbable sponge of the same diameter as the biopsy specimen is implanted into the biopsy site with the syringe. In one embodiment the circular sponge is cut from a pad with the biopsy punch.

In a second embodiment of the invention a small pre-formed surgical sponge is stored in the punch and implanted into a biopsy site with the syringe.

Fig. 1 is an end view of a biopsy device according to the present invention.

Fig. 2 is a front view of the biopsy device.

Fig. 3 is a cross-sectional view taken on the line 3-3 in Fig. 1.

Fig. 4 is a cross-sectional view taken on the line 4-4 in Fig. 2.

Fig. 5 is a front view showing the detachable needle removed from the syringe biopsy device and a small pad of an open cell surgical sponge.

Fig. 6 is a cross-sectional view of the syringe taken in the same manner as Fig. 3 with the plunger of the syringe depressed to extract a portion of the surgical sponge from the end of the syringe.

Fig. 7 is an end view of an alternate embodiment.

Fig. 8 is a cross-sectional view taken on the line 8-8 in Fig. 7.

Fig. 9 is a front view of the alternate embodiment showing the needle removed from the syringe.

Fig. 10 is a cross-sectional view taken on the line 10-10 in Fig. 9.

Fig. 11 is a cross-sectional view of the syringe taken in the same manner as Fig. 8 with the plunger of the syringe depressed to extract a surgical sponge from the syringe.

Fig. 12 is an end view of the alternate embodiment with the plunger of the syringe rotated clockwise 90 degrees.

Fig. 13 is a front view of a tool for removing the needle from the syringe.

Fig. 14 is an end view of the tool.

Fig. 15 is an enlarged fragmentary portion of Fig. 8.

Fig. 16 is a longitudinal cross-sectional view of an alternate embodiment.

Fig. 17 is a front view of an alternate embodiment.

Fig. 18 is a longitudinal cross-sectional view of the alternate embodiment of Fig. 17.

Fig. 19 is an enlarged fragmentary portion of Fig. 17.

Fig. 20 is an enlarged fragmentary portion of Fig. 18.

Referring now to the drawings wherein like numerals designate like and corresponding parts throughout the several views, a disposable device 20 for performing a skin biopsy is shown in Figs. 1 through 6, inclusive, according to the invention.

The biopsy device is comprised of a syringe 21, a thin sharp cylindrical punch 22 pressed into an aperture 23 of a cylindrical end portion 24 of the syringe 21, a detachable needle 25 attached to the outside of same end portion 24 and an absorbable surgical sponge 26. The punch 22 is exposed when the needle 25 is removed from the syringe 21.

The punch 22 is a thin cylindrical blade with a sharp end portion 27. In the embodiment 49 shown in Figs. 17 through 20, a punch 50 is formed from the same piece as a body 51 of a syringe 52 and has sharp serrations 53 at the end of the punch 50.

The construction of the syringe 21 is best seen in Figs. 3 and 6. The syringe 21 has a transparent plastic body 28 and a cylindrical plunger 29 which is slideably mounted in the body 28. The exterior of the body 28 has graduations 30 for measuring the amount of anesthetic in the syringe 21.

At one end of the plunger 29 there is a knob 31 for sliding the plunger 29 in and out of the body 28. The diameter of the other end of the plunger 29 is reduced for extracting a biopsy specimen (not shown) and the surgical sponge 26 from the punch 22. At an intermediate position on the plunger 29 there is a groove 32 which receives an O-ring 33 to seal the plunger 29 in the body 28.

In Fig. 16 an embodiment 54 is shown wherein the groove 32 and O-ring 33 are provided at the end portion of a plunger 55. The embodiment 36 requires a forceps (not shown) for extracting a biopsy specimen and sponge from the punch 22.

With reference to Fig. 5, a sponge 36 is cut from a rectangular pad 34 of a porous material which is absorbed completely by a patient with little tissue reaction. When the sponge 26 is implanted into a bleeding site, the sponge 26 absorbs blood, swells and terminates the flow of blood. By filling up the biopsy site, the sponge 26 promotes healing without the necessity of suturing.

One material which has been evaluated and found to be acceptable is an absorbable gelatin sponge manufactured by the Upjohn Company under the registered trademark "GELFOAM". It is a water-insoluble, off-white, non-elastic, porous, pliable product made from purified pork skin gelatin USP granules and is available in the form of pads.

The manner of using our invention is as follows. The syringe 21 is either pre-filled with a local anesthetic or filled in a conventional manner by withdrawing the plunger 29 from the body 28 with the end of the needle 25 immersed in the anesthetic. The anesthetic is then administered through the needle 25 into a biopsy site. The needle 25 is removed with the flat bladed tool 35 shown in Figs. 13 and 14 by engaging the notched portion 36 of the tool 35 with the end portion 37 of the syringe 21 and prying the needle 25 loose from the syringe 21. A small cylindrical specimen is excised from the patient by pressing the sharp end of the punch 22 against a patient's skin and rotating the body of the syringe 21.

After the specimen has been excised, the specimen is extracted from the punch 22 by sliding the plunger 29 into the syringe's body 28. The plunger 29 is then displaced rearward a small distance in the body 28 to provide space for the surgical sponge 26. The punch 22 is pressed and rotated against a small pad of surgical sponge 26 to cut out a cylindrical portion of the pad 34 of about the same diameter as the cylindrical defect caused by removal of the specimen from the patient. The surgical sponge 26 is implanted into a biopsy site by sliding the plunger 29 forward in the body 28 to extract the cylindrical sponge 26 from the punch 22 and to implant the sponge 26 into the defect caused by the excising of the biopsy specimen.

In Figs. 8-12 and 15, an embodiment 38 is illustrated wherein a pre-cut open cell surgical sponge 39 is stored in a biopsy punch 40. In this embodiment, the anesthetic passes through the pre-cut sponge 39 when the syringe 41 is filled and when the anesthetic is administered to the patient.

With reference to Fig. 12, the sponge 39 is positioned a small distance apart from the knife edge portion 42 of the punch 40. The innermost end of the punch 40 has an inward facing flange portion 43 to prevent the sponge 39 from being drawn into the body 44 of the syringe 41 during the filling of the syringe 41 with the anesthetic. On the upper part of the body 44, there is a stop 45 which prevents ejection of the sponge 39 during the administration of the anesthetic.

When additional plunger travel is needed to extract a biopsy specimen from the punch 40 or to implant the sponge 39 into a biopsy site, additional travel is obtained, as shown in Figs. 11 and 12, by rotating the plunger 46 ninety degrees to align the stop 45 with a groove 47 in the knob 48 of the body 44. One benefit of this embodiment 38 is a reduction in time for performing a biopsy. Another benefit is reduced likelihood of infection because handling is reduced.

The alternate embodiment 38 is used in a similar manner to the first embodiment, except that the plunger 46 is rotated ninety degrees to extract the specimen from the punch 40 and to implant the sponge 39 into the biopsy site.

From the foregoing it will be understood that our invention provides a device and method which reduces the time for performing a routine skin biopsy, reduces the likelihood of forming excessive scar tissue and protects medical personnel against infections.

Although several embodiments of our invention have been illustrated and described, it is not our intention to limit our invention to these embodiments since other embodiments can be provided by substitutions in materials and modifications in the shape, number and arrangements of parts and steps in our closure device and changes in steps in our method without departing from the invention as claimed.

Claims

1. A device for performing a skin biopsy procedure comprising in combination a syringe; a detachable needle mounted on the end of the syringe; and a thin cylindrical punch mounted on the same end of the syringe as said needle, said punch being only available for excising a specimen for analysis from a patient when said needle is removed from the end of said syringe.

2. A device according to claim 1, further comprising an open cell sponge for repairing a site from which said specimen has been excised.

3. A device according to claim 2, wherein said sponge is a pre-cut cylindrical sponge stored in the interior of said punch.

4. A device according to claim 2 or 3, wherein said sponge is a porous and pliable product made from purified pork skin.

5. A device according to any preceding claim, further comprising a means for removing said needle from the end of said syringe.

6. A device for performing a skin biopsy procedure comprising: the combination of a syringe, said syringe having a transparent body, a plunger slideably mounted on said body, said plunger having one end portion which is adapted for extracting said specimen from a biopsy punch and a seal mounted at an intermediate position on said plunger; a detachable needle mounted on the end of the syringe; and a thin cylindrical biopsy punch fixed to the same end of the syringe as said needle, said punch being only available for excising a specimen for analysis from a patient when said needle is removed from the end of said syringe.

7. A device according to claim 6, wherein the punch is made from the same piece as said body.

8. A device according to claim 6 or 7, further comprising a plurality of sharp serrations at an end portion of said punch.

9. A method for performing a skin biopsy procedure comprising the steps of: filling a syringe with a local anaesthetic; administering said anaesthetic to a biopsy site of a patient; removing a needle from the end of said syringe to expose a biopsy punch mounted on the end of said syringe; excising a specimen of skin with a sharpened end of said punch from said biopsy site; extracting said specimen from said biopsy punch by depressing a plunger of said syringe; retracting said plunger to space the end of said plunger from the end of said sharpened end of said punch; cutting a cylindrical portion of an open cell surgical sponge with said biopsy punch; and implanting said cylindrical portion of said open cell sponge into a wound caused by said excising of said specimen.

10. A method for conducting a skin biopsy procedure, comprising the steps of: filling a syringe with a local anaesthetic; administering said anaesthetic to a biopsy site of a patient; removing a needle from the end of said syringe to expose a biopsy punch mounted on the end of said syringe; rotating said plunger of said syringe to increase the maximum travel of said plunger; excising a specimen of skin with a sharpened end of said punch from said biopsy site; extracting said specimen from said biopsy punch by depressing a plunger of said syringe; implanting said cylindrical open cell sponge portion into a wound caused by said excising of said specimen.

11. The method according to claim 10, further comprising the step of applying pressure to said sponge for 30 to 60 seconds.

12. A method according to claim 10 or 11, further comprising the step of cleaning and draping said biopsy area before the excising of said specimen.

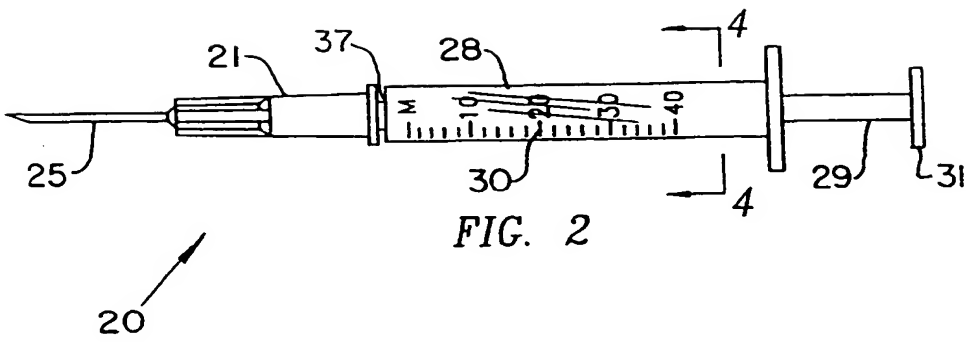

FIG. 2

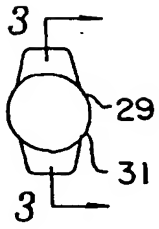

FIG. 1

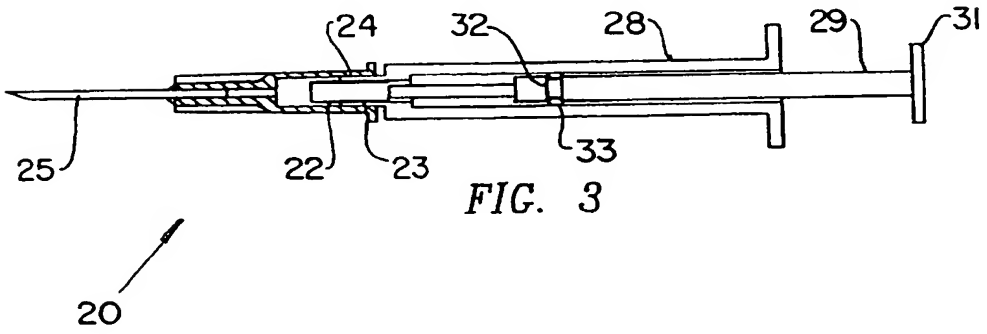

FIG. 3

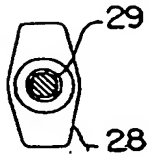

FIG. 4

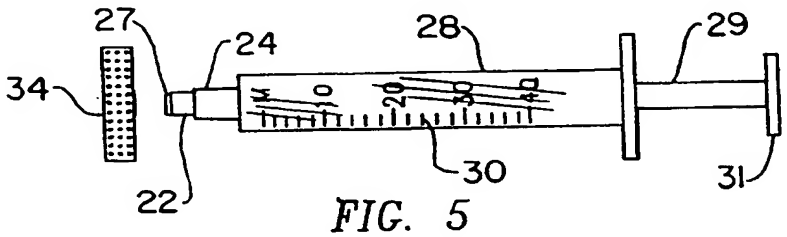

FIG. 5

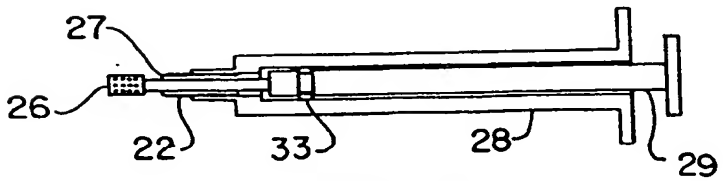

FIG. 6

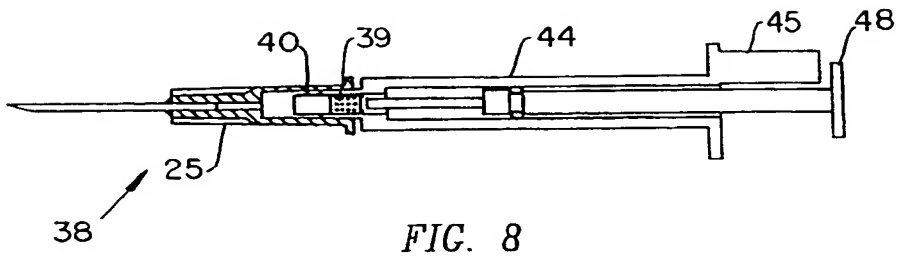

FIG. 8

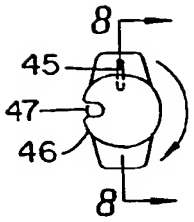

FIG. 7

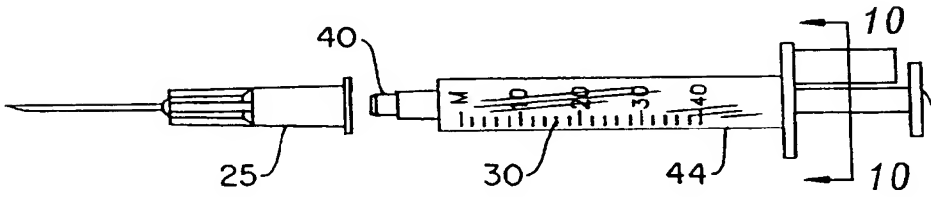

FIG. 9

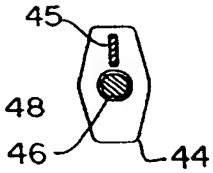

FIG. 10

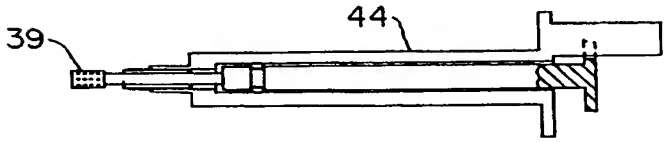

FIG. 11

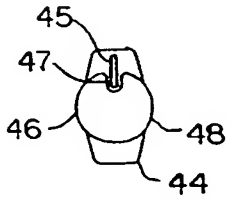

FIG. 12

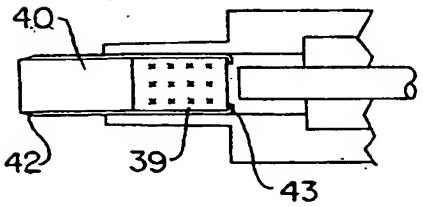

FIG. 15

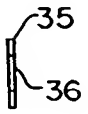

FIG. 14

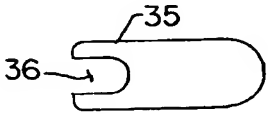

FIG. 13

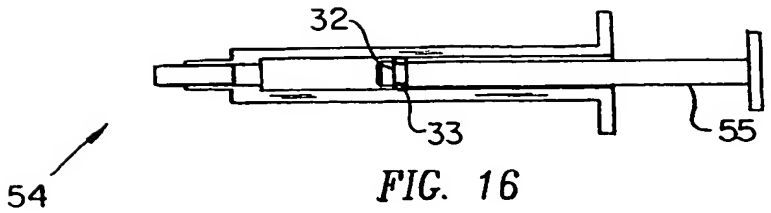

FIG. 16

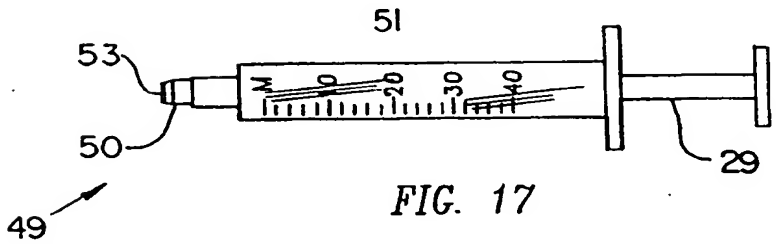

FIG. 17

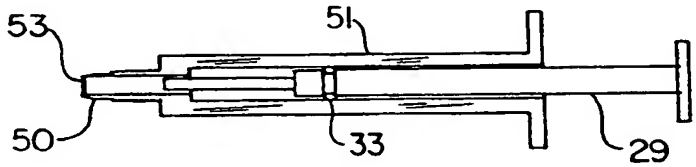

FIG. 18

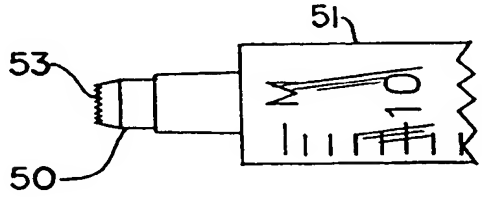

FIG. 19

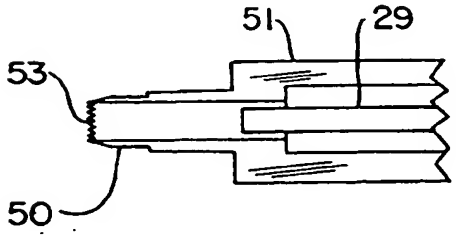

FIG. 20

European Patent Office

PARTIAL EUROPEAN SEARCH REPORT

which under Rule 45 of the European Patent Convention shall be considered, for the purposes of subsequent proceedings, as the European search report

Application Number EP 94 30 3934

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.6)
X A	US-A-2 868 201 (GABRIEL) * column 2, line 5 - line 25; figures 3,1 * ---	1 1	A61B10/00 A61M5/00
A	EP-A-0 243 341 (IMMUNO) * page 4, line 21 - page 5, line 36; figures 9,10 * ---	1,6	
A	WO-A-88 05668 (MEDICORP) * page 10, paragraph 3 4; figures 3,4 * ---	1,6	
A	CH-A-534 505 (REINISCH) * claims 1,7,9; figure 1 * ---	1,6	
A	DE-A-19 05 232 (GAAST) * claim 1; figure 1 * ---	1,6	
A	US-A-5 053 010 (MCGARY ET AL.) * claim 1; figures 1,3,5 * ---	1,6	
A	WO-A-86 06951 (SCHNEPP-PESCH) * page 10, paragraph 2; figure 4 * --- -/--	6	

TECHNICAL FIELDS SEARCHED (Int.Cl.6)

A61B
A61M

INCOMPLETE SEARCH

The Search Division considers that the present European patent application does not comply with the provisions of the European Patent Convention to such an extent that it is not possible to carry out a meaningful search into the state of the art on the basis of some of the claims

Claims searched completely :

Claims searched incompletely :

Claims not searched :

Reason for the limitation of the search:

see sheet C

Place of search	Date of completion of the search	Examiner
THE HAGUE	5 October 1994	Moers, R

CATEGORY OF CITED DOCUMENTS

X : particularly relevant if taken alone
Y : particularly relevant if combined with another document of the same category
A : technological background
O : non-written disclosure
P : intermediate document

T : theory or principle underlying the invention
E : earlier patent document, but published on, or after the filing date
D : document cited in the application
L : document cited for other reasons

& : member of the same patent family, corresponding document

EPO FORM 1503 03.82 (P04C07)

European Patent Office

PARTIAL EUROPEAN SEARCH REPORT

Application Number
EP 94 30 3934

DOCUMENTS CONSIDERED TO BE RELEVANT			CLASSIFICATION OF THE APPLICATION (Int.Cl.6)
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	
A	US-A-4 838 280 (HAAGA) * abstract; figures 4,5,8,9 *	2	
			TECHNICAL FIELDS SEARCHED (Int.Cl.6)

EPO FORM 1503 03.82 (P04C10)

INCOMPLETE SEARCH

Claims searched completely : 1-8
Claims not searched : 9-12

Reason : Method for treatment of the human or animal body by surgery (Art 52(4) EPC).